K061936

SMDA Information

AUG - 9 2006

Summary of Safety and Effectiveness

Submitted by:	The Kendall Company 15 Hampshire Street Mansfield, MA 02048
Contact Person:	Paul W. Evans (508) 261-8203
Date Prepared:	July 7, 2006
Proprietary Name:	Kendall Argyle® 1.9 Fr Dual Lumen Neonatal/Pediatric Peripherally Inserted Central Catheter
Common Name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	Long-term catheters (30 days or more)
Predicate Devices:	Kendall Argyle 2.0 Fr. Single Lumen PICC (K974015) Kendall Argyle 1.9 Fr. Dual Lumen PICC (K42461)

Description of the Device:

The Argyle 1.9 Fr Neonatal/Pediatric Peripherally Inserted Central Catheter PICC) is a dual lumen polyurethane tube that bifurcates into two 5.0 Fr polyurethane tubes (pigtails), the proximal ends of the tubes ending in insert molded hubs. One pigtail is longer than the other. The primary longer lumen will be clear. The shorter secondary lumen will be tinted a lavender color to distinguish it from the primary lumen.

Intended Use of the Device:

The proposed PICC catheter is designed for cases in which venous catheterization or long term I.V. administration is necessary in the neonate or pediatric patient. Placement is routinely achieved by a peripheral venous site. The catheter may be used to administer fluids simultaneously for hydration and parenteral nutrition, as well as other commonly used intravenous medications.

K061936

Technological Characteristics:

The Argyle Neonatal / Pediatric PICC is equivalent to the referenced predicate devices in that they are fabricated from similar materials, have the same function, equivalent indications for use, and similar overall design.

Nonclinical testing:

Biocompatibility testing was performed on the Argyle PICC catheter, following ISO-10993 Biological Evaluation of Medical Devices. The testing found that the materials used in the Kendall Argyle PICC catheter are biocompatible.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 9 2006

The Kendall Company
Mr. Paul W. Evans
Director, Regulatory Affairs
Division of Tyco Healthcare Group LP
15 Hampshire Street
Mansfield, Massachusetts 02048

Re: K061936
Trade/Device Name: Kendall Argyle® 1.9 Fr Dual Lumen Neonatal/Pediatric Peripherally Inserted Central Catheter
Regulation Number: 880.5970
Regulation Name: Percutaneous, Implanted, Long Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: July 7 2006
Received: July 10, 2006

Dear Mr. Evans:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

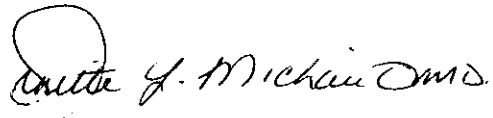
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K061936

Device Name: Kendall / Argyle 1.9 Fr Neonatal / Pediatric Peripherally Inserted Central Catheter (PICC)

Indications for Use:

The catheter is designed for cases in which venous catheterization or long term I.V. administration is necessary. Placement is routinely achieved from a peripheral venous site, but the catheter may be placed via subclavian cutdown as well. The catheter may be used to administer fluids for hydration and parenteral nutrition, as well other commonly used intravenous medications.

Prescription Use ✓ OR Over-The Counter Use_____
(Per 21 CFR §801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

(510(k) Number: K061936